




UNITED STATES PATENT AND TRADEMARK OFFICE


UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,591	12/05/2001	Katherine S. Bowdish	ALEX-P01-055	3521
28120 7590 08/27/2007 FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			EXAMINER SCHLAPKOHL, WALTER	
			ART UNIT 1636	PAPER NUMBER
			MAIL DATE 08/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/006,591	Applicant(s) BOWDISH ET AL.	
	Examiner Walter Schlapkohl	Art Unit 1636	<i>Waf</i>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/31/2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 23, 24, 26-37, 73, 74, 85-96 and 101-104 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 23, 24, 26-37, 73, 74, 85-96 and 101-104 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1636

DETAILED ACTION

Receipt is acknowledged of the papers filed 4/2/2007 and 5/31/2007 in which claims 1, 23, 33-36, 85 & 92 were amended and claims 97-100 were cancelled. Claims 1-6, 23-24, 26-37, 73-74, 85-96 and 101-104 are pending and under examination in the instant Office action.

Any rejection of record not recited herein is hereby
WITHDRAWN.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/31/2007 has been entered.

Art Unit: 1636

The following is a quotation of the first paragraph of 35

U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 23-24, 26-37, 73-74, 85-96 and 101-104 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This rejection is maintained for reasons of record.

Response to Arguments

Applicant argues that Examiner appears to have broadly interpreted the claims because of the alleged indefinite recitation of "anneals specifically." Applicant further argues that the recited phrase "anneals specifically during a polymerase reaction to" has been amended to "complementary to" to expedite prosecution. Applicant further argues that the specification provides specific examples of the claimed primer sequences and the collar sequences such as SEQ ID NOs: 3-4 which

Art Unit: 1636

anneal to a portion of the kappa light chain and SEQ ID NOS: 7-8 which anneal to a portion of the heavy CH1 constant region and that these sequences are representative of the claimed genus. Applicant also argues that the level of skill and knowledge in the art regarding construction of plasmids directed to a target nucleic acid is very high, and a skilled artisan can readily envision other primer sequences and collar sequences which anneal to a desired target nucleic acid sequence.

Applicant's arguments have been carefully considered but are respectfully found unpersuasive. Applicant's assertion that the disclosed primer and collar sequences of SEQ ID NOS: 3-4 and 7-8 are representative of the claimed genus is not persuasive because the claimed genus encompasses any primer or any collar sequence of about 10 or more nucleotides having any degree of complementarity with any polypeptide-encoding portion of a nucleic acid. Limitation of such sequences to those which are "from about 10 nucleotides to about 50 nucleotides or more" and which are "complementary to" at least a first or second portion of a polypeptide encoding portion of a nucleic acid does not render the genus significantly narrower as any degree of complementarity is encompassed. Examiner agrees with Applicant insofar as the level of skill and knowledge in the art regarding construction of plasmids directed to a target nucleic acid is

Art Unit: 1636

very high, and that the skilled artisan can readily envision other primer sequences and collar sequences which anneal to a desired target nucleic acid sequence. However, one of ordinary skill in the art would also know that the claimed genus of sequences encompassed by Applicant's claims is extremely large, reading upon practically any nucleic acid of about 10 nucleotides or more. Disclosure of SEQ ID NOs: 3-4 and 7-8 is therefore not representative of the genus. Furthermore, Examiner wishes to emphasize that the record has established that the inventive portion of the subject matter at hand is the technical feature of the primer sequence and the collar sequence and that this fact raises the standard for written description in the instant case insofar as such technical features (sequences) are the Applicant's invention. It is therefore more important that Applicant teach one of ordinary skill in the art how to both make and use the claimed inventive features in such a way as to reasonably convey to one skilled in the relevant art that Applicant, at the time the application was filed, had possession of the claimed invention.

Claims 101-104 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not

Art Unit: 1636

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. This rejection is maintained for reasons of record but has been slightly altered in order to accommodate Applicant's amendment.

The specification as originally filed does not provide support for the invention as now claimed: "wherein said primer sequence is at least 15 nucleotides and said collar sequence is at least 15 nucleotides" (claims 101-104). The specification does not provide sufficient blazemarks nor direction for the instant primer/collar sequence length ranges encompassed by the above-mentioned limitation, as currently recited. The instant claims now recite limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Response to Arguments

Applicant argues that they disagree with the rejection under 35 U.S.C. 112, first paragraph, written description (new

Art Unit: 1636

matter). Applicant further argues that claims 1, 23, 85 and 92 have been amended to recite a primer sequence or a collar sequence "from about 10 nucleotides to about 50 nucleotides or more." Applicant believes that the claim amendments obviate the new matter rejection.

Applicant's arguments have been carefully considered and have respectfully been found unpersuasive. While Applicant's amendment to claims 1, 23, 85 and 92 have rendered the rejection moot with respect to those claims, Applicant has not amended claims 101-104 which recites a range not disclosed in the specification. Therefore, the claim amendments do not obviate the new matter rejection in its entirety.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 23-24, 26-32, 37, 73-74, 85-98 and 101-104 are rejected under 35 U.S.C. 102(b) as being anticipated by Young et al (PNAS 80:1194-1198, 1983; of record). This rejection is

Art Unit: 1636

maintained IN PART for reasons of record but has been extended to claims 85-96 and 103-104 and comprises new grounds of rejection not necessitated by Applicant's amendment.

For purposes of this rejection, portions of polypeptide encoding nucleic acids, including portions of antibody encoding portions of mRNA (e.g., claim 23) and portions encoding constant regions of a light chain of an antibody (e.g., claim 29), have been given the broadest reasonable interpretation; the recited phrases have been interpreted to include portions which are only a single nucleotide in length as long as the nucleotide falls within the coding sequence of the mRNA. Thus, any primer sequence or collar sequence that is complementary to at least one nucleotide within a polypeptide-encoding portion of an mRNA (or other nucleic acid) is also complementary to at least one nucleotide within an "mRNA encoding at least a portion of an antibody" or "a portion of the mRNA encoding a framework region" or "a portion of the mRNA encoding a constant region of an antibody."

Young et al teach a λ gt11 expression vector with multiple PvuI cloning sites within the lacZ coding sequence wherein the lacZ sequences 5' of the first PvuI site and 3' of the fourth PvuI site are the respective "collar" and "primer" sequences complementary to portion of a polypeptide/antibody/constant

Art Unit: 1636

region/framework region encoding portion of a nucleic acid wherein the portions are separated by at least 20 nucleotides in length and said separating sequence comprises at least one or two restriction sites (see entire document, especially Figure 1). Because only a portion (one nucleotide) of the primer sequence and the collar sequence need be complementary, the claim limitations are met by the λ gt11 expression vector. Furthermore, because the primer and collar sequences are those just 5' and 3' of the respective PvuI sites in the λ gt11 expression vector, the primer and collar sequence adjoin to create a restriction site. Using the first PvuI site and the fourth PvuI sites as boundaries for the primer and collar, the primer and collar sequences are separated by 1.65 kb. The λ gt11 expression vector was present in a host cell (see Young et al at page 1195, Table 1), thus meeting the claim limitations of claims 6, 37 and 96.

Claims 23-24, 26-32, 37, 74, 85-96, 99-100 and 103-104 are rejected under 35 U.S.C. 102(b) as being anticipated by Kohno et al (*Gene* 188:175-181, 1997; of record). This rejection is maintained for reasons of record.

Art Unit: 1636

Response to Arguments

Applicant argues that the Advisory Action appears to indicate that Applicant's response and amendment submitted on 3/28/2007 have overcome the rejection of the claims under 35 U.S.C. 102(b) as anticipated by both the Kohno et al and the Young et al references. Applicant further argues that the plasmid of claim 1 features that the first portion and the second portion of the polypeptide encoding portion of the nucleic acid are separated by at least 20 nucleotides and that Young et al fail to teach or suggest this feature. Applicant also argues that Young et al fail to teach or suggest the claims limitations recited in claims 23, 85 and 92 wherein a portion of a nucleic acid encodes an antibody, the framework region associated with an antibody or the constant region associated with antibody.

Applicant's arguments have been carefully considered and have respectfully been found unpersuasive. Examiner has reviewed the Advisory Action mailed 4/25/2007 and does not see where it was indicated or suggested that Applicant's submission of 3/27/2007 was remedial to overcome the rejections of the claims under 35 U.S.C. 102(b). Furthermore, such an argument is moot since Applicant has since modified the claims as they were presented in the amendment filed 3/27/2007; the instantly

Art Unit: 1636

rejected claims are based upon a further amendment filed 5/31/2007. As set forth above, Examiner has provided a clear explanation of how the reference by Young et al meets the claim limitations. The rationale has been slightly altered to further clarify how the primer and collar sequences are separated by at least 20 nucleotides. Applicant's assertion that Young et al fail to teach or suggest the claim limitations recited in claims 23, 85 and 92, i.e. portions of a nucleic acid encoding an antibody, the framework region associated with an antibody, or the constant region associated with antibody is not persuasive because the plasmid taught by Young et al does comprise primer sequences comprising adenine, guanine, thymine and cytosine nucleotides which are complementary to those present in cDNAs and/or mRNAs encoding antibodies or portions of antibodies. As the claims are written, Young et al need not explicitly teach a plasmid encoding an antibody or a portion of antibody in order for the claim limitations to be anticipated; such portions would inherently be comprised of A, G, T and C nucleotides, at least one of which is complementary to a nucleic acid present both in the primer and in the collar. With regard to the Kohno et al reference, Applicant is reminded that the collar and primer sequences are separated by at least 20 nucleotides as evidenced by the presence of the HIS5 gene (1158 nucleotides long;

Art Unit: 1636

sequence provided in the action mailed 7/14/2005). Importantly, the HIS5 gene located between the collar and primer sequences contains numerous restriction sites as also evidenced by the *S. cerevisiae* HIS4 gene sequence obtained from the Saccharomyces Genome Database).

Conclusion

No claim is allowed.

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant does submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-

Art Unit: 1636

9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Joseph Woitach can be reached at (571) 272-0739.

Walter A. Schlapkohl, Ph.D.
Patent Examiner
Art Unit 1636

August 17, 2007


DAVID GUZO
PRIMARY EXAMINER